Risk Communication Advisory Committee
Meeting: February 25-26, 2010
Background and Discussion Topics

Below is a selection of communications that FDA has previously issued. Please consider them only as selected examples of some general **Types of Communication Challenges**, as noted below and on the agenda. As you proceed in your discussion and comment, please also note the **Bulleted List of Questions for Committee Comment,** further below.

Types of Communication Challenges

- FDA seeks to ensure that healthcare professionals know about new or updated safety information about a product and carefully monitor their patients who use the product. At the same time, FDA also wants to ensure that relevant patients know about the safety information and that FDA is addressing the issue. However, FDA does not want to cause undue alarm.

  Examples:
  - External Biphasic Defibrillators
  - Electri-cord Power Cords
  - Gardasil labeling revision (syncope)
  - Meridia (sibutramine hydrochloride)
    - Initial Early Communication about ongoing safety review
    - Follow-up communication

- FDA seeks to ensure that all product users know about new or updated safety-related information and understand what both healthcare professionals and patients or caregivers should do about the new information.

  Examples:
  - Tysabri (natalizumab)
    - Drug Safety Communication
    - Earlier Posting on Drug Safety Communication
  - Multi-slice CT Machines Update
  - Glucose Monitoring Test Strips
    - For Healthcare Professionals
    - For Patients
  - NSAIDS for dogs-owners, NSAIDS for pain control in dogs

- FDA seeks to ensure that healthcare professionals and the public know about an ongoing investigation, where those affected by the risk may be of special concern to the population at large.

  Examples:
  - NSAIDS for Pain Control in Dogs, see previous links
  - Use of Influenza A (H1N1) 2009 Monovalent Influenza Vaccine in Pregnant Women
  - Common Ingredients in US Licensed Vaccines

- FDA seeks to ensure that healthcare professionals and the public know about how to use a product appropriately in a crisis or emergency situation where the regulatory status of the product is a key factor in understanding appropriate use.

  Examples:
  - Powerheart AED (Cardiac Science)
  - Tamiflu and Relenza (permitting use of outdated product for H1N1)
    - For Healthcare Professionals
    - For Public
  - H1N1 Fraudulent Products Widget

- FDA seeks to inform a broad and diverse public by reaching out through multiple channels.

  Examples:
  - H1N1 Fraudulent Products Widget
  - NSAIDS for Pain Control in Dogs, see previous links

Bulleted List of Questions for Committee Comment

- Are the messages clear and understandable?
- Does the communication answer all of your questions or does it leave you wanting more information?
- Does the communication's title make it obvious what it is about?
- Is there a category of information that is missing from the communication's format, or is additional background information needed about FDA's decision?
- Do the formatting and content convey clearly the purpose of the communication?
- Is the communication presented at a level that is appropriate for the target audience(s)?
- Are the headers (if applicable) understandable?
- Do the recommendations meet the needs of the target audiences?
- Would you change your behavior/take appropriate action based on this communication? If not, why?